SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL:	SB 468
INTRODUCER:	Senators Klein, Smith and Margolis
SUBJECT:	Biomedical Research
DATE:	April 22, 2006
REVISED:	04/24/06

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Bedford	Wilson	HE	**Fav/1 amendment**
2.			CM	
3.			CJ	
4.			GO	
5.			HA	
6.			JA	

Please see last section for Summary of Amendments

- [ ] Technical amendments were recommended
- [x] Amendments were recommended
- [ ] Significant amendments were recommended

I. Summary:

This bill creates the Florida Better Quality of Life and Biomedical Research Act (the act). The bill funds embryonic and adult stem cell research under the act by using $15 million from the Biomedical Research Trust Fund annually, for 10 consecutive years. It specifies that the Department of Health Institutional Review Board (IRB) shall not review research funded through the act. The bill creates the Biomedical Research and Ethics Oversight Council to review research funded by this act. The bill creates the Biomedical Research Advisory Council to advance stem cell research and funding sources for the state. The bill provides duties for the advisory council. It requires the advisory council to submit an annual report on the state of biomedical research in the state to the Florida Center for Universal Research to Eradicate Disease, the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30.

The bill creates a grants-in-aid program to fund stem cell research. The bill restricts the use of such funds for research on embryonic stem cells to cells taken from donated leftover embryos from in vitro fertilization treatments. The bill requires the department to develop and maintain on its Internet website a consent form for the donation of embryos for stem cell research. The bill prohibits the purchase or sale of embryonic fetal tissue for research purposes and establishes a penalty. It also prohibits human reproductive cloning and establishes a penalty.

The Department of Health will be responsible for implementing the grants-in-aid program and supporting the two councils created

This bill amends ss. 20.435 and 381.86, F.S.

This bill creates s. 381.99, F.S.

II. Present Situation:

Department of Health/Institutional Review Boards

The Department of Health (DOH or department) institutional review boards (IRBs) review all state funded research involving human subjects, including research involving stem cells under s. 381.86, F.S. The Secretary of Health appoints board members, chairs, and co-chairs of the DOH IRBs. The department maintains compliance with all applicable federal regulations and guidance. The DOH IRBs meet twice a month.

The department currently staffs three other legislatively created research programs with advisory councils. The James and Esther King Biomedical Research Program, the Florida Cancer Center, and the Florida Center for Universal Research to Eradicate Disease (CURED). The James and Esther King Biomedical Research program is similar to the proposed Florida Better Quality of Life and Biomedical Research Act.

The James and Esther King Biomedical Research Program

The 1999 Legislature established the Lawton Chiles Endowment Fund (ch. 99-167, L.O.F.), through which the state uses funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research.
Section 215.5602, F.S., establishes the James and Esther King Biomedical Research Program funded from earnings of the endowment fund and provides that funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. The research conducted may include stem cell related research.

Section 215.5602(3), F.S., creates the nine-member Biomedical Research Advisory Council in the department. The council must advise the Secretary of Health as to the direction and scope of the biomedical research program.

Federal Regulations

In November 2001, President George W. Bush created The President's Council on Bioethics "to advise the President on issues that may emerge as a consequence of advances in biomedical science and technology."[1] In particular, the council was authorized to study ethical issues

[1] Executive Order #13237

connected with specific technological activities such as embryo and stem cell research. After studying the issue of human cloning, the majority, ten members of the council, voted to ban cloning for the production of children and to place a four-year moratorium on cloning for biomedical research. The minority, seven members, voted to ban cloning for the production of children and to regulate the use of cloned embryos for research.

There are four primary sources for embryonic stem cells: existing stem cell lines, aborted or miscarried embryos, unused in vitro fertilized embryos, and cloned embryos. Current federal policy limits federally funded research to research conducted on embryonic stem cell lines created before August 2001. There are currently more than 60 existing different human embryonic stem cell lines that have been developed from excess embryos created for in vitro fertilization with the consent of the donors and without financial inducement. These existing lines are used in approximately one dozen laboratories around the world (in the United States, Australia, India, Israel, and Sweden). Federal funding of research involving cloning for the purpose of reproduction or research is prohibited. However, there is no federal law banning human cloning altogether. The Food and Drug Administration has claimed authority over the regulation of human cloning technology as an investigational new drug and stated that at this time, they would not approve any projects involving human cloning for safety reasons, but Congress has not passed legislation confirming the FDA's authority to prohibit cloning.[2]

Stem Cell Legislation in Other States

Many state legislatures have been particularly interested in the stem cell debate. In 2005, states considered over 170 bills on embryonic and adult stem cell research. More than a dozen states will carry over legislation, and others will consider new bills. Should embryonic stem cell research be legal? Should state funds support it? Should the state fund adult stem cell research instead? These are some of the questions lawmakers are asking nationwide in 2006.[3] California and New Jersey have taken the lead in supporting stem cell research. Both states have struggled with regulatory issues. California has chosen to create a mini-National Institute of Health (NIH) to oversee research, whereas New Jersey has centralized research.

Stem Cells

Stem cells are unique and unspecialized cells. The purpose of stem cells in the adult body is to replace cells normally lost due to age, injury, or disease. Two properties make stem cells unique from other cells:

- Stem cells can divide thousands of times without error and without breaking down. Scientists can cause one stem cell to produce hundreds of identical stem cells in what is called a line.

[2] State Embryonic and Fetal Research Laws, National Conference of State Legislatures, 2005.
[3] Challenges in 2006, Contemplating Stem Cell Research, National Conference of State Legislatures, January 2006.

- Stem cells can differentiate into a variety of different cells. Scientists can induce stem cells to become cells with special functions, such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.[4]

There are differences between adult and embryonic stem cells. Adult stem cells are limited in the variety of cells into which they can differentiate and generally only develop into the cell types of the tissue from which they were isolated.[5] Embryonic stem cells are more flexible and can be triggered to produce a range of specialized cells. After an egg is fertilized, it begins to divide from one cell into two, then from two cells into four, and so on. In the first few divisions, each embryo cell contains the ability to make all the cells in the human body. As the embryo continues to divide, the cells begin to specialize into particular organ cells. It is for this reason that the most "useful" stem cells are those that have not yet passed the first few divisions.[6] This quality is important because it permits such stem cells to be used to address a variety cures and treatments for disease.

A significant debate about stem cells involves the source of the cells. Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). Human embryos are the source for pluripotent stem cells—cells that are capable of giving rise to most tissues of the human organism. The development of embryos for the sole purpose of harvesting the stem cells is considered immoral by many because the embryo is killed. For this same reason, the harvesting of stem cells from any embryo is considered immoral by many.

Reproductive Cloning

Reproductive cloning is the cloning of a human embryo for the purposes of initiating a pregnancy. The debate over reproductive cloning heated up when "Dolly" the sheep was successfully cloned in 1997. Federal funding for cloning research is prohibited and 13 states have passed laws prohibiting reproductive cloning.[7] Several others have banned state funding for reproductive cloning. Florida is one of the many states that have not weighed in on the issue. This bill bans reproductive cloning.

Ethical Issues

A central ethical issue surrounding embryonic stem (ES) cell research involves the status of the human embryo. In general, the stances that people hold on this issue depend on two factors: (1) beliefs on the status of the embryo, and (2) the context in which embryos are acquired and used. In terms of the status of the fetus, stances vary from "embryos are human individuals and should never be used for research," to "embryos are a mere cluster of cells and may be created for the sole purpose of research." The majority of people gravitate to a position between the two stances,

[4] Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. www.bioethics.umn.edu/publications/bo/Stem_Cells.pdf (last visited April 21, 2006).
[5] Stem Cell Basics. National Institutes of Health. http://stemcells.nih.gov/index.asp. (last visited April 21, 2006).
[6] Hudson, K.L., Scott, J., and Faden, R. 2005. Values in Conflict: Public Attitudes on Embryonic Stem Cell Research. A Report from the Genetics and Public Policy Center. www.DNApolicy.org. (last visited on April 21, 2006).
[7] National Conference of State Legislatures, State Human Cloning Laws, 2005.

holding for example that embryos are "more than just cells," but they do not have the same status as a fetus or baby, and can therefore be used to derive stem cells for research.[8]

In terms of the context in which embryos are acquired, stances also vary. For many people who believe that human life begins at conception, it is wrong to create embryos for the purpose of destroying them; however it is acceptable to use already existing embryos that are left over from in vitro fertilization procedures and would be discarded anyway. This principal is referred to as the "nothing is lost" principle and means if an embryo is not going to be used for its original purpose of reproduction and would be discarded in the future, science should be allowed to make use of the embryo prior to its destruction, for research that might benefit people who are alive and suffering from a disability or illness.[9]

Florida Center for Universal Research to Eradicate Disease (CURED)

Florida's Center for Universal Research to Eradicate Disease (CURED) was created by the Florida Legislature in its 2004 Regular Session. Section 381.855, F.S., established the program and created an advisory council to provide policy recommendations to the Legislature. The program is appropriated $250,000 from the annual administrative expenses allocated to the James and Esther King Biomedical Research program. The fiscal year 2005-2006 budget did not include any full-time staff positions.

The CURED seeks to coordinate, improve, expand and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread use. It seeks to promote research programs that identify cures to cancer, heart and lung disease, diabetes, autoimmune disorders and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.

As part of the enabling legislation for the CURED, the program is charged with holding an annual biomedical technology summit in Florida. The CURED is also directed to monitor the supply and demand needs of researchers relating to stem cell research and other types of human tissue research. However, given its limited budget, the CURED has not yet held an annual biotechnology summit. However, one is planned for summer 2006. The CURED also has not started monitoring the supply and demand of stem cells in Florida and does not plan to in the immediate future.[10]

Scripps Florida Funding Corporation

Senate Bill 6E passed during the 2003E legislative session created s. 288.955, F.S., which creates a not-for-profit organization known as the Scripps Florida Funding Corporation (corporation) for the purpose of receiving, holding, and investing, administering, and disbursing funds appropriated by the Legislature for the establishment and operation of a state-of-the-art

[8] Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. www.bioethics.umn.edu/publications/bo/Stem_Cells.pdf (last visited on April 21, 2006).
[9] Hudson, K.L., Scott, J., and Faden, R. 2005. Values in Conflict: Public Attitudes on Embryonic Stem Cell Research. A Report from the Genetics and Public Policy Center. www.DNApolicy.org. (last visited on April 21, 2006).
[10] Annual Report of the Advisory Council of The Florida Center for Universal Research to Eradicate Disease, 2005.

biomedical research institution in this state. The funding corporation was responsible for negotiating and executing a contract with the Scripps Research Institute to accomplish this goal.

Currently, Florida is moving ahead with the creation of a Scripps Research Institute. It is likely the Institute will be built in one of the south Florida communities.

III. Effect of Proposed Changes:

Section 1. Amends s. 20.435, F.S., to change the source of funds deposited into and the use of funds in the Biomedical Research Trust Fund. Funds in the trust fund must be used for the purposes of the Florida Better Quality of Life and Biomedical Research Act created in the bill, in addition to the James and Esther King Biomedical Research Program.

Section 2. Amends s. 381.86, F.S., regarding the Institutional Review Board in DOH, to specify that the IRB shall review human subjects research except for research involving human embryonic or adult stem cells, and to specify that such research must instead be reviewed by the Biomedical Research and Ethics Oversight Council created in the bill.

Section 3. Creates s. 381.99, F.S., entitled the "Florida Better Quality of Life and Biomedical Research Act".

Subsection (1) provides that s. 381.99, F.S., may be cited as the "Florida Better Quality of Life and Biomedical Research Act."

Subsection (2) defines the following terms: adult stem cell, asexual reproduction, embryonic stem cells, human reproductive cloning, in vitro fertilization, oocyte, and stem cells.

Subsection (3) provides legislative findings regarding acute, chronic, and degenerative diseases that could potentially be treated as a result of biomedical research. In order to maintain a high quality of life for Floridians, research into stem cell regenerative therapies and treatments should be supported. The state should bolster and advance Florida's biotechnology industry, research, and cooperation between the state's colleges, universities, and private-sector research.

Subsection (4) establishes the Biomedical Research Advisory Council (note that there currently exists another body with this name as provided in s. 215.5602, F.S., and nothing in this bill amends s. 215.5602, F.S.). The advisory council consists of seven members appointed as follows: two persons appointed by the Governor, one by the President of the Senate, one by the Speaker of the House of Representatives, one by the Minority Leader of the Senate, and one by the Minority Leader of the House of Representatives. The Secretary of Health shall serve as chair of the advisory council. Members shall have specific experience and knowledge in stem cell research, biomedical research, bioethics, and business and financial investments. Members may not serve more than two consecutive two year appointments. Appointments must be made by October 1, 2006, and the first meeting must take place no later than November 1, 2006. The council must meet at least twice per year, but no more than four times per year. Members may be reimbursed for per diem and travel expenses.

This advisory council must work to provide an environment fostering the advancement of embryonic and adult stem cell research. The advisory council must: develop a recommendation for a donated-funds program; examine and identify specific ways to improve and promote embryonic and human adult stem cell research; develop a recommendation for a grant program to advance embryonic or human adult stem cell research, by December 1, 2006; develop an application for this grant program; after December 1, 2006, receive applications and make recommendations for grant awards; and monitor research institutions receiving grant funding.

The bill requires the advisory council to submit an annual progress report on the state of biomedical research in the state to the Florida Center for Universal Research to Eradicate Disease, the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30 and specifies the content of the report. (The Biomedical Research Advisory Council of the James and Esther King Biomedical Research Program is required to submit an annual progress report on the state of biomedical research – s. 215.5602(10), F.S.) It requires council members to disclose any conflict of interest or potential conflict of interest to the Secretary of Health. The bill requires DOH to provide administrative staff to assist the advisory council in developing a grant application form, reviewing grant applications received, making recommendations to the council, preparing a written consent form described in paragraph (7)(b) of this bill, and performing other functions as the council requires.

Subsection (5) creates a seven-member Biomedical Research and Ethics Oversight Council and specifies the membership to include the Secretary of Health as Chair and two persons appointed by the Governor, one by the President of the Senate, one by the Speaker of the House of Representatives, one by the Minority Leader of the Senate, and one by the Minority Leader of the House of Representatives. Members must have specific experience and knowledge in stem cell research and related areas. Members must serve four-year terms but may not serve for more than two consecutive four-year terms. The first meeting must be no later than November 1, 2006. Members must meet at least twice but no more than four times per year. Members may receive per diem and travel expense reimbursement.

The bill charges The Biomedical Research and Ethics Oversight Council with the responsibility of reviewing research involving embryonic and human adult stem cells that is funded or supported through the Biomedical Research Trust Fund to ensure adherence to ethical and safety guidelines of the United States Department of Health and Human Services. Federal regulations (45 CFR 46 and 21 CFR 50 and 56) require review of research involving stem cells. The Biomedical Research and Ethics Oversight Council would be required to review protocols under these regulations and would serve as another IRB from the perspective of federal regulations and the Department's Federalwide Assurance.

Subsection (6) specifies that the Secretary of Health will make grants-in-aid in accordance with the provisions in this section. The bill requires the department to require any applicant for a grant-in-aid to submit an application containing certain information and provides that the advisory council (not the oversight council) will make recommendations to the Secretary of Health after considering the recommendations of the oversight council.

This bill establishes that, beginning with the 2006-2007 fiscal year, and for 10 consecutive years thereafter, no less than $15 million will be made available from the Biomedical Research Trust

Fund for grants-in-aid for embryonic or human adult stem cell research. Any year end balance not used for grants-in-aid shall be carried forward for the fiscal year next succeeding such grants-in-aid.

Subsection (7) requires funds provided under this section to be used only for research involving human adult stem cells and human embryonic stem cells taken from donated leftover embryos from in-vitro fertilization treatments. The bill requires a physician or other health care provider who is treating a patient for infertility to give that patient information sufficient to allow the person to make an informed and voluntary choice regarding disposition of any embryos remaining after infertility treatment. It specifies that a person given such information must be presented with the options of storing embryos, donating them to another person, donating them for research purposes, or selecting other means of disposition. If donating for research purposes, the person must give written consent using the form provided by the department. It also provides for a second degree felony for certain behaviors relating to buying or selling embryonic fetal tissue for research.

Subsection (8) prohibits human reproductive cloning and provides for penalties.

Section 4. Provides an effective date of July 1, 2006.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

There will expenses associated with seeking approval from the Biomedical Research and Ethics Oversight Council for stem cell research funded from the Biomedical Research Trust Fund. To the extent that researchers at private universities and institutions receive

research grants there is a positive impact. Depending on the outcome of such research there may be additional funding from other sources, patents, and licensure/royalty income. To the extent that funded research leads to commercial products, the biotechnology and pharmaceutical industries will benefit, as will residents if jobs are created.

As a result of the funding provided by the proposed program, positive effects are anticipated: increased recognition of Florida as a leader in biomedical research and biotechnology and a favorable location for new or growing business; increased competitiveness for national funding and increased ability to attract top scientists to the state; increased likelihood that treatments and cures are found; and growth of a clean, high-paying employment market.

C. Government Sector Impact:

This bill provides $15 million for the proposed grants-in-aid program and requires the department to provide the staff and resources necessary to support the Biomedical Research Advisory Council found in this language. Although not mentioned in the proposed bill, additional staff and resources will be needed to support the Biomedical Research and Ethics Oversight Council. Unless the department is allowed to use up to 15 percent of the $15 million for administrative expenses the department would be faced with absorbing the entire cost of providing this support using its allotted general revenue. The department would need to add staff, expand office space, and provide other resources to accommodate three FTEs, including a 0.5 FTE attorney for the increased legal work associated with the project. Additionally, while s. 381.86, F.S., allows the DOH IRB to charge fees to support its review of human subjects research, the proposed bill requires that stem cell research be reviewed pursuant to the provisions of s. 381.99, F.S., which does not provide for the recovery of partial costs. Lost fees are estimated at $30,500 for year one and $50,000 for year two.

Estimated Expenditures	**1st Year**	**2nd Year (Recur.)**
Salaries*		
0.5 Senior Attorney @ $50,000	$32,000	$32,960
0.5 Legal Secretary @ $32,000	$20,480	$21,094
1 Program Administrator @ $55,000	$70,400	$72,512
0.5 Program Assistant @ $32,000	$20,480	$21,094
0.5 IRB Admin. Assistant@ $32,000	$20,480	$21,094
Subtotal	**$163,840**	**$168,754**
Expenses		
0.5 FTE Professional, limited travel	$11,060	$5,978
0.5 FTE Support Staff	$8,148	$3,380
1 FTE Professional, maximum travel	$21,393	$10,783
0.5 FTE Professional, limited	$11,060	$5,978
0.5 FTE Support Staff	$8,148	$3,380

Annual Report	$20,000	$20,000
Application & peer review process**	$472,809	$330,700
Program marketing, info. Dissemination	$5,000	$5,000
Travel for two councils	$7,644	$7,873
Additional IRB expense***	$30,250	$30,250
Subtotal	**$595,510**	**$423,322**
Total Estimated Expenditures	**$759,350**	**$592,076**
IRB Revenue		
20 initial reviews****	$30,000	$30,000
10 amendments year one	$5,000	$0
20 amendments year two	$0	$10,000
20 continuing reviews	$0	$10,000
Total Estimated IRB Revenue	**$35,000**	**$50,000**
Net Expenditures	**$724,350**	**$542,076**

* FTEs are computed w/ 28 percent fringe and 3 percent base salary increase for second year.
** Estimates based on the James and Esther King Biomedical Research Program cost. First year is higher for one time only development costs.
*** Mostly additional education for members and office supplies.
**** Estimated based on awarding 20 three-year grants at a total of $750,000 per grant. The number of amendments is a guess.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Biomedical Research and Ethical Oversight Council

The bill does not make clear that the Biomedical Research and Ethical Oversight Council created in s. 381.99, F.S., is an institutional review board and must comply with federal and state regulations governing research involving humans. The term “institutional review board” is a generic term used to describe the entity in an institution that is responsible for ensuring the health and safety of persons participating in research. It may be called by a different name, but it is still an institutional review board. The lack of clarity in the bill further complicates the ability of the Council to charge for research review. Currently under s. 381.86(5), F.S., the DOH institutional review board (IRB) may assess fees to support the review of human subject research.

In s. 215.5602, F.S., there is another body named the Biomedical Research Advisory Council; however, the bill does not amend s. 215.5602, F.S. The bill should provide a unique name for the advisory council it creates to avoid confusion.

Section 381.99, F.S., specifies that the Biomedical Research and Ethical Oversight Council will meet at least twice annually, but no more than four times annually. According to the Department of Health, institutional review boards (IRBs) generally receive application for reviews and amendments on an ongoing basis. Limiting the number of times an IRB committee may meet, would create unnecessary delays in research because the research can not continue until approval is received.

Grant-in-Aid Funding

Previous bills creating a grant program have used the same or similar language as established in, s. 215.5602, F.S., for the James and Esther King Biomedical Research Program. One key component of the grants disseminated for the James and Esther King Biomedical Research Program is an unbiased peer review process. According to the Department of Health, a peer review process is critical to the success of a grant-in-aid program. The grant-in-aid funding program in the Florida Better Quality of Life and Biomedical Research Act does not provide for an unbiased peer review process.

VIII. Summary of Amendments:

Barcode 740844 by Health Care :
The amendment requires the Secretary of Health to determine and appoint the membership of the Institutional Review Board in the Department of Health. It also designates a separate review committee for stem cell research funded under s. 381.99, F.S.

The amendment removes the definition for asexual reproduction and oocyte. It also changes the Biomedical Research Advisory Council to be the Stem Cell Research Advisory Council. The Biomedical Research and Ethics Oversight Council is changed to the Stem Cell Ethics Institutional Review Board. There is a separate committee established within this board that will have oversight of the research. The board will now meet at least twice a year and as often as necessary, but no more than once per month.

The amendment allows up to 15 percent of the annual appropriation to be made available for administrative costs. The amendment adds an appropriation of $15 million annually for the next 10 years from the General Revenue Fund to the Biomedical Research Trust Fund for the purposes of the Florida Better Quality of Life and Biomedical Research Act. (WITH TITLE AMENDMENT)